

(43) International Publication Date 6 January 2005 (06.01.2005)

PCT

(10) International Publication Number WO 2005/001142 A2

(51) International Patent Classification⁷: C07H 21/00, A61K 48/00

C12Q 1/68,

(21) International Application Number:

PCT/US2004/020356

(22) International Filing Date: 23 June 2004 (23.06.2004)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data: 10/602,494

23 June 2003 (23.06.2003) US

- (71) Applicant (for all designated States except US): EPIGE-NOMICS AG [DE/DE]; Kastanienalle 24, 10435 Berlin (DE).
- (72) Inventors; and

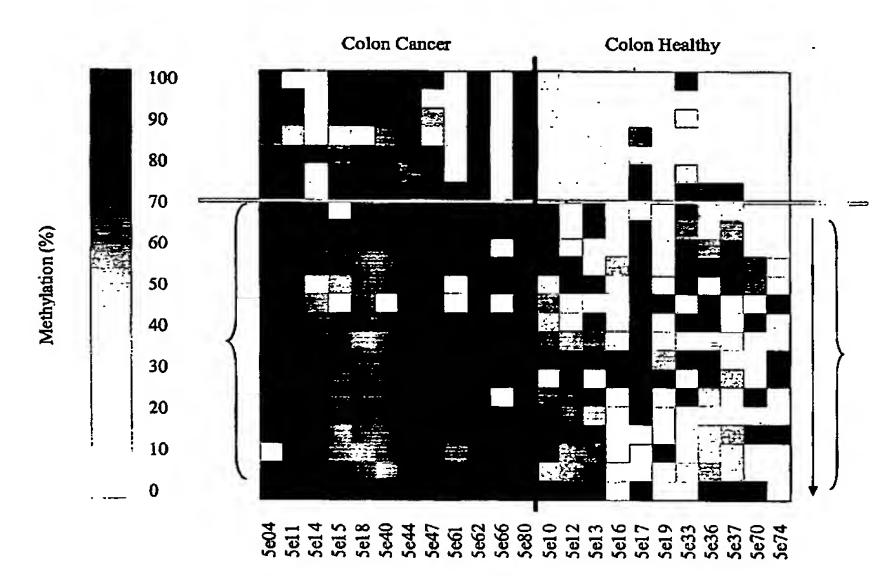
(75) Inventors/Applicants (for US only): LOFTON-DAY, Cathy [US/US]; 23908 35th Avenue W., Brier, WA 98036 (US). SLEDZIEWSKI, Andrew [US/US]; 17736 15th Avenue NW, Shoreline, WA 98177 (US). THOMAS, Jeff [US/US]; 12210 NE 24th Street, Apt. 109, Bellevue, WA 98005 (US). DAY, Robert, W. [US/US]; 1872 East Hamlin

Street, Seattle, WA 98112 (US). TONNES-PRIDDY, Lori [US/US]; 1914 Grand Avenue, Apt. B, Everett, WA 98201 (US). CARDON, Karen [US/US]; 17730 151st Avenue SE, Apt. E, Renton, WA 98058 (US).

- (74) Agents: DAVISON, Barry, L. et al.; 2600 Century Square, 1501 Fourth Avenue, Seattle, WA 98101-1688 (US).
- (81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.
- (84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI,

[Continued on next page]

(54) Title: METHODS AND NUCLEIC ACIDS FOR THE ANALYSIS OF COLORECTAL CELL PROLIFERATIVE DISORDERS



(57) Abstract: Various aspects of the present invention provide novel diagnostic and prognostic methods for detecting, or for detecting and differentiating between or among colorectal cell proliferative disorders. Preferably, said colorectal cell proliferative disorders are selected from the group consisting of colorectal carcinoma, colon adenomas, and colon polyps. The inventive methods are based on analysis of differential CpG dinucleotide methylation of genomic DNA between or among normal and disease states. Additional embodiments provide nucleic acids and oligomers (including oligonucleotides and peptide nucleic acid (PNA)-oligomers), nucleic acid arrays and kits useful for practicing said methods, and in otherwise detecting, or detecting and differentiating between or among colorectal cell proliferative disorders.

BEST AVAILABLE COPY

WO 2005/001142 A2



FR, GB, GR, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

Published:

 without international search report and to be republished upon receipt of that report (43) International Publication Date 6 January 2005 (06.01.2005)

PCT

(10) International Publication Number WO 2005/001142 A3

(51) International Patent Classification⁷: C07H 21/00, A61K 48/00

C12Q 1/68,

(21) International Application Number:

PCT/US2004/020356

(22) International Filing Date: 23 June 2004 (23.06.2004)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data: 10/602,494

23 June 2003 (23.06.2003) US

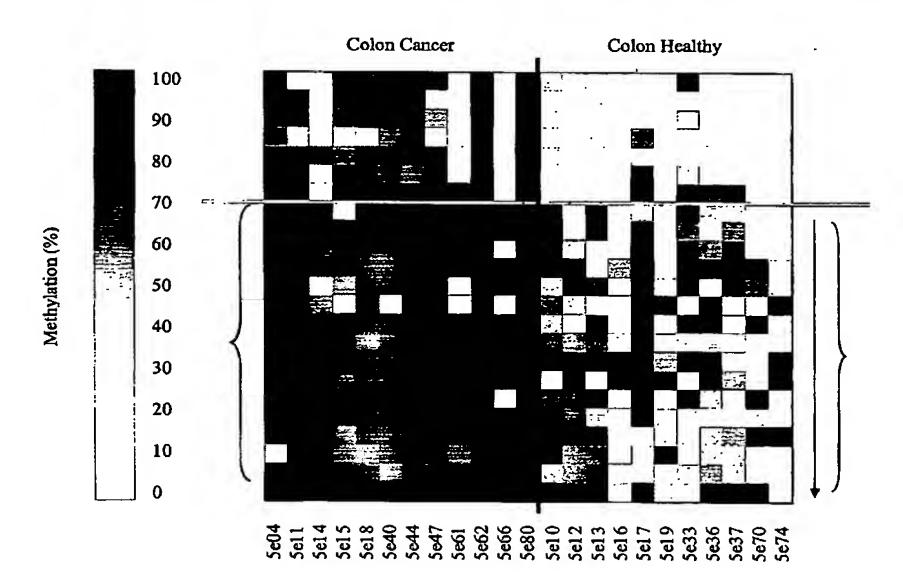
- (71) Applicant (for all designated States except US): EPIGE-NOMICS AG [DE/DE]; Kastanienalle 24, 10435 Berlin (DE).
- (72) Inventors; and
- (75) Inventors/Applicants (for US only): LOFTON-DAY, Cathy [US/US]; 23908 35th Avenue W., Brier, WA 98036 (US). SLEDZIEWSKI, Andrew [US/US]; 17736 15th Avenue NW, Shoreline, WA 98177 (US). THOMAS, Jeff [US/US]; 12210 NE 24th Street, Apt. 109, Bellevue, WA

98005 (US). DAY, Robert, W. [US/US]; 1872 East Hamlin Street, Seattle, WA 98112 (US). TONNES-PRIDDY, Lori [US/US]; 1914 Grand Avenue, Apt. B, Everett, WA 98201 (US). CARDON, Karen [US/US]; 17730 151st Avenue SE, Apt. E, Renton, WA 98058 (US).

- (74) Agents: DAVISON, Barry, L. et al.; 2600 Century Square, 1501 Fourth Avenue, Seattle, WA 98101-1688 (US).
- (81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.
- (84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI,

[Continued on next page]

(54) Title: METHODS AND NUCLEIC ACIDS FOR THE ANALYSIS OF COLORECTAL CELL PROLIFERATIVE DISORDERS



(57) Abstract: Various aspects of the present invention provide novel diagnostic and prognostic methods for detecting, or for detecting and differentiating between or among colorectal cell proliferative disorders. Preferably, said colorectal cell proliferative disorders are selected from the group consisting of colorectal carcinoma, colon adenomas, and colon polyps. The inventive methods are based on analysis of differential CpG dinucleotide methylation of genomic DNA between or among normal and disease states. Additional embodiments provide nucleic acids and oligomers (including oligonucleotides and peptide nucleic acid (PNA)-oligomers), nucleic acid arrays and kits useful for practicing said methods, and in otherwise detecting, or detecting and differentiating between or among colorectal cell proliferative disorders.

BEST AVAILABLE COPY

WO 2005/001142 A3



FR, GB, GR, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

with international search report

(88) Date of publication of the international search report:
15 December 2005

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.